that the Subcommittee on Energy of the Committee on Energy and Natural Resources will hold a hearing on Saturday, December 6, 2003 at 9 a.m. The hearing will be held at the Paducah Information Age Park, 2000 McCracken Blvd., Paducah, KY.

The purpose of the hearing is to conduct oversight and accounting of the cleanup at the Department of Energy's Paducah, KY site.

Because of the limited time available for the hearing, witnesses may testify by invitation only. However, those wishing to submit written testimony for the hearing record should send two copies of their testimony to the Committee on Energy and Natural Resources, United States Senate, SD–364, Washington, DC 20510–6150.

For further information, please contact Pete Lyons (202–224–5861) or Shane Perkins (202–224–7555).

AUTHORITY FOR COMMITTEES TO MEET

JOINT ECONOMIC COMMITTEE

Mr. MCCAIN. Mr. President, I ask unanimous consent that the Joint Economic Committee be authorized to conduct a hearing in room 628 of the Dirksen Senate Office Building, Friday, November 7, 2003, from 9:30 a.m. to 1 p.m.

The PRESIDING OFFICER. Without objection, it is so ordered.

PRIVILEGES OF THE FLOOR

Mr. DORGAN. Mr. President, I ask unanimous consent Jason Estep, a fellow from my office, have floor privileges for today.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. DURBIN. Mr. President, I ask unanimous consent that Dale Jones, a member of my staff, be granted the privilege of the floor during debate on S. 150.

The PRESIDING OFFICER. Without objection, it is so ordered.

BLACKWATER NATIONAL WILDLIFE REFUGE EXPANSION ACT

The PRESIDING OFFICER. I ask unanimous consent that the Senate proceed to the immediate consideration of Calendar No. 356, H.R. 274.

The PRESIDING OFFICER.

The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (H.R. 274) to authorize the Secretary of the Interior to acquire the property in Cecil County, Maryland, known as Garrett Island for inclusion in the Blackwater National Wildlife Refuge.

There being no objection, the Senate proceeded to consider the bill.

Mr. FRIST. I ask unanimous consent that the bill be read the third time and passed, the motion to reconsider be laid upon the table, and any statements be printed in the RECORD.

The PRESIDING OFFICER. Without objection, it is so ordered.

The bill (H.R. 274) was read the third time and passed.

ANIMAL DRUG USER FEE ACT OF 2003

Mr. FRIST. I ask unanimous consent that the Chair now lay before the Senate a message from House of Representatives on the bill (S. 313) to amend the Federal Food, Drug, and Cosmetic Act to establish a program of fees relating to animal drugs.

There being no objection, the Presiding Officer laid before the Senate the following message from the House of Representatives:

S. 313

Resolved, That the bill from the Senate (S. 313) entitled ''An Act to amend the Federal Food, Drug, and Cosmetic Act to establish a program of fees relating to animal drugs'', do pass with the following amendment; Strike out all after the enacting clause and insert:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Animal Drug User Fee Act of 2003''.

SEC. 2. FINDINGS.

Congress finds as follows:

(1) Prompt approval of safe and effective new animal drugs is critical to the improvement of animal health and the public health.

(2) Animal health and the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for review of new animal drug applications.

(3) The fees authorized by this Act will be dedicated toward expediting the animal drug development process and the review of new and supplemental animal drug applications and investigational animal drug submissions as set forth in the goals identified, for purposes of part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Energy and Commerce of the House of Representatives and the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate as set forth in the Congressional Record.

SEC. 3. FEES RELATING TO ANIMAL DRUGS.

Subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f et seq.) is amended by adding at the end the following part:

''PART 4—FEES RELATING TO ANIMAL DRUGS

''SEC. 739. DEFINITIONS.

''For purposes of this subchapter:

''(1) The term 'animal drug application' means an application for approval of any new animal drug submitted under section 512(b)(1). Such term does not include either a new animal drug application submitted under section 512(b)(2) or a supplemental animal drug application.

''(2) The term 'supplemental animal drug application' means—

''(A) a request to the Secretary to approve a change in an animal drug application which has been approved; or

''(B) a request to the Secretary to approve a change to an application approved under section 512(c)(2) for which data with respect to safety or effectiveness are required.

''(3) The term 'animal drug product' means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an animal drug application or a supplemental animal drug application has been approved.

''(4) The term 'animal drug establishment' means a foreign or domestic place of business which is at one general physical location consisting of one or more buildings all of which are within 5 miles of each other, at which one or more animal drug products are manufactured in final dosage form.

''(5) The term 'investigational animal drug submission' means—

''(A) the filing of a claim for an investigational exemption under section 512(j) for a new animal drug intended to be the subject of an animal drug application or a supplemental animal drug application, or

''(B) the submission of information for the purpose of enabling the Secretary to evaluate the safety or effectiveness of an animal drug application or supplemental animal drug application in the event of their filing.

''(6) The term 'animal drug sponsor' means either an applicant named in an animal drug application, except for an approved application for which all subject products have been removed from listing under section 510, or a person who has submitted an investigational animal drug submission that has not been terminated or otherwise rendered inactive by the Secretary.

''(7) The term 'final dosage form' means, with respect to an animal drug product, a finished dosage form which is approved for administration to an animal without substantial further manufacturing. Such term includes animal drug products intended for mixing in animal feeds.

''(8) The term 'process for the review of animal drug applications' means the following activities of the Secretary with respect to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions:

''(A) The activities necessary for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

''(B) The issuance of action letters which approve animal drug applications or supplemental animal drug applications or which set forth in detail the specific deficiencies in animal drug applications, supplemental animal drug applications, or investigational animal drug submissions and, where appropriate, the actions necessary to place such applications, supplements or submissions in condition for approval.

''(C) The inspection of animal drug establishments and other facilities undertaken as part of the Secretary's review of pending animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

''(D) Monitoring of research conducted in connection with the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

''(E) The development of regulations and policy related to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

''(F) Development of standards for products subject to review.

''(G) Meetings between the agency and the animal drug sponsor.

''(H) Review of advertising and labeling prior to approval of an animal drug application or supplemental animal drug application, but not such activities after an animal drug has been approved.

''(9) The term 'costs of resources allocated for the process for the review of animal drug applications' means the expenses incurred in connection with the process for the review of animal drug applications for—

''(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees consulted with respect to the review of specific animal drug applications, supplemental animal